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Bayer Healthcare Pharmaceuticals Inc.

**IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY**

BAYER HEALTHCARE
PHARMACEUTICALS INC.,

Plaintiff,

v.

RJ HEALTH SYSTEMS
INTERNATIONAL LLC,

Defendant.

Civil Action No. 2:15-CV-06952-KM-
MAH

Document Electronically Filed

FIRST AMENDED COMPLAINT

FIRST AMENDED COMPLAINT FOR DAMAGES AND OTHER RELIEF

Plaintiff Bayer HealthCare Pharmaceuticals Inc. (“BHCP”) brings this Complaint against Defendant RJ Health Systems International LLC (“RJ Health”) seeking damages and other relief.

NATURE OF THE ACTION

1. RJ Health recklessly disseminated false and misleading information about two distinct forms of birth control—Mirena® and Liletta®—marketed and sold in the United States by BHCP and Actavis, respectively. These products provide distinct benefits and are sold at different prices. Nonetheless, RJ Health irresponsibly insisted on conflating them in its widely used drug-information databases, listing the same price for both of them.

2. This misinformation is significant and tremendously damaging to BHCP. As RJ Health knows and intends, the overwhelming majority of health insurance plans and other payors directly rely on defendant's pricing information in setting reimbursement policies. Because of RJ Health's misinformation, BHCP has lost millions of dollars in revenue.

3. Mirena® is a levonorgestrel-releasing intrauterine system that was first approved by the Food and Drug Administration ("FDA") in 2000. Mirena currently is approved for two indications: (1) intrauterine contraception, and (2) the treatment of heavy menstrual bleeding in women who choose intrauterine contraception as their method of contraception. Mirena is inserted into a patient's uterus by a healthcare provider in a simple office visit and is effective for up to five years.

4. Intrauterine systems like Mirena are generally recognized as the most effective form of non-permanent birth control. For instance, the American College of Obstetricians and Gynecologists ("ACOG") has opined that intrauterine systems are "top-tier contraceptives" and that other forms of birth control "have lower continuation rates and higher pregnancy rates." ACOG Committee Opinion No. 539 (Oct. 2012), <http://bit.ly/1mlm9WT>.

5. Mirena has been embraced by healthcare providers and patients alike. In the past 15 years, more than nine million units of Mirena have been sold in the United States. During

that time, millions of women and thousands of healthcare providers in the U.S. have become accustomed to using Mirena as birth control and to treat heavy menstrual bleeding.

6. BHCP sets the wholesale acquisition cost (“WAC”) for Mirena. The published WAC for Mirena throughout the relevant timeframe was \$810.51, which amounted to a monthly-weighted cost of \$13.51.

7. Liletta® is another levonorgestrel-releasing intrauterine system that was approved by FDA on February 26, 2015. Liletta is not Mirena, and it is not a generic version of Mirena. Liletta is a distinct system that uses a different insertion device, provides fewer benefits, must be replaced more frequently, and costs more per month to use.

8. Switching from Mirena to Liletta would pose several challenges for patients, healthcare providers, and payors:

- a. Liletta is approved in the United States for use for up to *three years*, whereas Mirena is approved for use for up to *five years*. A shorter useful life of Liletta imposes obvious burdens on patients, who would need to undergo more frequent intrauterine procedures if they were to switch from Mirena to Liletta.
- b. Liletta costs more per month than Mirena. The WAC for Liletta was set at \$625, which amounts to a monthly-weighted cost of \$17.36, compared to just \$13.51 for Mirena.
- c. Liletta is approved only for use as a contraceptive, which means that Liletta may not be appropriate for those prescribers and patients who rely on Mirena to treat heavy menstrual bleeding.
- d. Liletta uses a vastly different insertion device. Liletta’s insertion device requires two hands and multiple steps to properly load. The insertion device for Mirena, which is patented, is preloaded and can be operated with just one hand.

9. Unfortunately, RJ Health insisted on conflating Liletta and Mirena by providing the same price for both of them. RJ Health claims to sell “the most comprehensive, trusted and up-to-date drug coding and reimbursement information in the industry.” RJ Health claims that its products are “the industry standard for proper claim coding and processing” and are used by

more than “250 clients, including more than 110 payor organizations reaching over 110 million covered lives.”

10. The value that RJ Health provides is principally the “code price” that it creates according to its proprietary methodology. In general, RJ Health creates and disseminates a “code price” for certain billing and payment codes used in the healthcare industry to reimburse healthcare providers for pharmaceutical products administered to patients other than by oral method. On information and belief, RJ Health is the only company to provide this service, which is why so many of the nation’s leading health insurers have purchased subscriptions from RJ Health.

11. Although Mirena and Liletta are distinct products, with distinct benefits and prices, RJ Health listed the same “code price” for both of them: \$625. This code price was based on the published WAC for Liletta, not Mirena.

12. After FDA’s February 2015 approval of Liletta, BHCP repeatedly contacted and met with RJ Health to try to prevent these misstatements. BHCP explained that RJ Health’s error could cause significant harm to BHCP, patients, healthcare providers, and payors. Nevertheless, on June 1, 2015, RJ Health willfully chose to disseminate false and misleading information.

13. The consequences of RJ Health’s misrepresentations are far reaching and severe. On information and belief, many health insurance plans and other payors *automatically* load the information provided by RJ Health—including the code price—into their medical claims payment systems, and set reimbursement rates based on this purported “industry standard.” As a result, between July and October 2015, many payors updated their reimbursement policies and

reduced the reimbursement level they would pay for Mirena down to the misleading \$625 code price disseminated by RJ Health.

14. Healthcare providers cannot sustain financial losses on the products they purchase and prescribe. The reimbursement gap created by RJ Health's misstatements would have forced them to stop prescribing Mirena even if they or their patients preferred it. The resulting loss of market share and goodwill for BHCP would have been irreparable.

15. Due to RJ Health's actions, BHCP had to take immediate and drastic steps to mitigate the harm to itself and the public. Effective July 1, 2015, BHCP temporarily discounted the purchase price for Mirena to match the false reimbursement amount RJ Health communicated to payors. The intent of the temporary discount was to ensure that providers and patients are not harmed by RJ Health's knowing misconduct.

16. For these reasons, and those discussed below, BHCP seeks (i) compensatory damages for any lost sales of Mirena; (ii) compensatory damages equivalent to the temporary discount that RJ Health has forced BHCP to adopt for Mirena; (iii) trebled and/or punitive damages; (iv) disgorgement of RJ Health's profits; (v) costs; (vi) attorney fees; (vii) pre-judgment interest; (viii) post-judgment interest; and (ix) any other relief that the Court deems just under these circumstances.

PARTIES

17. Plaintiff Bayer HealthCare Pharmaceuticals Inc. ("BHCP") is a Delaware corporation with its principal place of business in New Jersey. As an inventor company, BHCP sets trends in research-intensive areas. The pharmaceuticals segment of BHCP focuses on the research and development of prescription products in a number of areas, including women's health. One of the women's health products marketed and sold by BHCP is Mirena.

18. On information and belief, Defendant RJ Health Systems International LLC (“RJ Health”) is a Connecticut limited liability company, with its principal place of business in Connecticut.

JURISDICTION AND VENUE

19. This Court has subject matter jurisdiction under 28 U.S.C. § 1332(a) because the amount in controversy exceeds \$75,000 and is between citizens of different states.

20. This Court also has subject matter jurisdiction because this action arises under the laws of the United States. 28 U.S.C. §§ 1331, 1367.

21. Venue is proper in this judicial district pursuant to 28 U.S.C. § 1391(b)(1), because Defendant is a corporation subject to personal jurisdiction in New Jersey and therefore “shall be deemed to reside” in this district. 28 U.S.C. § 1391(c)(2). Defendant conducts business with clients in New Jersey, and defendant is aware that its misrepresentations injured BHCP in New Jersey.

GENERAL ALLEGATIONS

I. Mirena® (levonorgestrel-releasing intrauterine system)

22. BHCP markets and sells Mirena®. Mirena is a levonorgestrel-containing intrauterine system recommended for women who have had at least one child. Levonorgestrel is a progestin—a synthetic version of the hormone progesterone—that is widely used in birth control products.

23. Mirena was first approved by FDA in December 2000 and currently is indicated for: (i) intrauterine contraception for up to five years, and (ii) treatment of heavy menstrual bleeding for women who choose to use intrauterine contraception as their method of contraception. Mirena® Package Insert (May 2014), <http://1.usa.gov/1B2rtHc>.

24. Mirena is one of the most effective non-permanent birth control methods on the market, with a failure rate of less than 1%. Government agencies and leading medical groups recommend the use of intrauterine systems such as Mirena to prevent unintended pregnancies, which are estimated to cost U.S. taxpayers over \$20 billion per year.

25. Mirena is the only five-year intrauterine system on the market, and the only available intrauterine system that is FDA-approved for the treatment of heavy menstrual bleeding in women who choose to use intrauterine contraception.

26. Mirena is placed in a patient's uterus by a healthcare provider during a routine office visit. Placement of Mirena does not involve a surgical procedure. With a patented insertion device, Mirena can be inserted using only one hand.

27. As soon as Mirena is placed in the patient's uterus by a healthcare provider, the intrauterine system starts releasing small amounts of levonorgestrel, which provides continuous birth control for up to five years.

28. BHCP has sold over 9 million units of Mirena in the 14 years since FDA approved the product. In 2014, BHCP sold more than 1 million units of Mirena in the U.S.

29. A wide variety of organizations across America, including health maintenance organizations (HMOs), hospitals, and physicians, purchase Mirena to provide to their patients. From November 17, 2014, through June 2016, Mirena's WAC had been set at \$810.51, which equated to a cost of approximately \$13.51 per month, when divided across the five-year period for which the product is indicated by FDA.

II. Liletta® (levonorgestrel-releasing intrauterine system)

30. On February 26, 2015, FDA approved another levonorgestrel-releasing intrauterine system called Liletta pursuant to an NDA submitted by Actavis under 21 U.S.C. § 355(b)(2). *See* Liletta Approval Ltr. (Feb. 26, 2015), <http://1.usa.gov/1L1rWg5>.

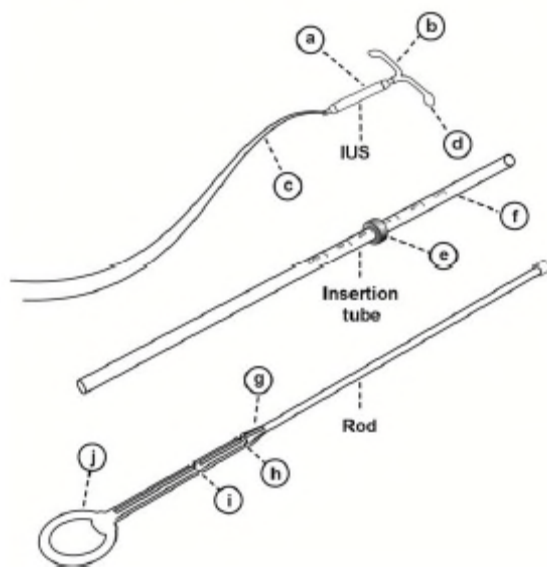
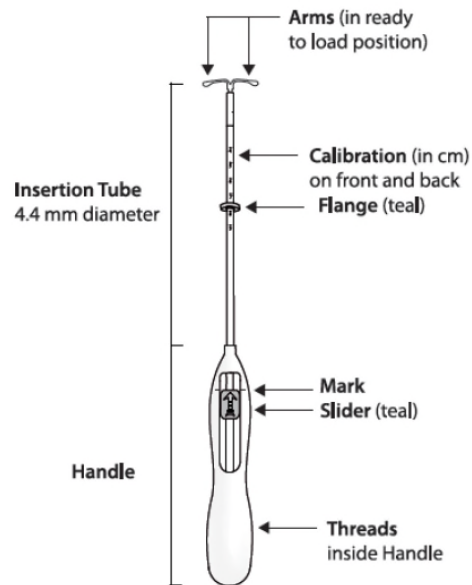
31. Liletta is *not* Mirena; nor is it a generic version of Mirena. Liletta is a distinct single source drug. At the time of approval, FDA designated Liletta to be a “new product.” FDA, *Orange Book*, Patent and Exclusivity Search Results for Appl. No. N206229 (June 9, 2015), <http://1.usa.gov/1BYXFWM>.

32. Liletta is not interchangeable for Mirena. At the time of approval, FDA determined that Liletta is not therapeutically equivalent to any other product. *See* FDA, *Orange Book*, OB_Rx Search Results for Appl. No. N206229 (June 9, 2015), <http://1.usa.gov/1JFzDYX>.

33. As reflected in the FDA-approved labeling, significant therapeutic distinctions exist between Liletta and Mirena. First, patients using Liletta will need to undergo more frequent intrauterine procedures than patients using Mirena. Liletta is indicated only for prevention of pregnancy for up to *three* years, and a patient who has been prescribed Liletta must have the system removed after three years. *See* Liletta® Package Insert (Feb. 2015), <http://1.usa.gov/1B2x0O6>. Mirena, however, provides up to *five* years of contraception—patients who have been prescribed Mirena can keep the system in place for up to five years.

34. Second, Liletta is not indicated for treatment of heavy menstrual bleeding in women who choose an intrauterine system for contraception. Mirena is the only intrauterine system approved by FDA to provide that additional benefit.

35. Third, Liletta uses a vastly different insertion system compared to Mirena’s patented inserter. The approved package inserts for the two products contain the following significantly different diagrams of their respective insertion systems:

Figure 2: LILETTA IUS with Inserter**Mirena and Inserter**

As the diagrams show, Liletta's inserter consists of a tube and plunger, which requires the healthcare provider to follow multiple steps to properly load the device and to place the product using two hands. In contrast, Mirena consists of a patented, preloaded device that allows for single-handed use. Healthcare providers accustomed to Mirena may find Liletta more difficult to insert correctly.

36. In addition, Liletta is more expensive to use than Mirena. The WAC for Liletta was set at \$625, which equated to a cost of \$17.36 per month. Mirena is a five-year product, so it is cheaper on a per-month basis (\$13.51 per month for a WAC of \$810.51).

III. RJ Health

37. RJ Health maintains a portfolio of drug-information resources, including resources covering drug coding, pricing and reimbursement. RJ Health's resources are available to its subscribers through its website, ReimbursementCodes.com, in printed form, and in ASCII or Excel format. According to RJ Health, it sells "the only comprehensive system that uses proven methodology to validate and update the price of each drug code, delivering the most

current information available.” <http://rjhealthsystems.com/drug-info-resources.php#reimbursementcodes>.

38. RJ Health’s products play a key role in drug reimbursement. RJ Health’s marketing and advertising materials assert that more than 110 payors rely on its products and those payors collectively cover more than 110 million patients.

39. On information and belief, RJ Health’s customers use the information they receive from RJ Health, including the “code prices” created by RJ Health, to periodically update their reimbursement systems. When this is done, the information published by RJ Health, and specifically the “code price” calculated and disseminated by RJ Health, is automatically used to adjudicate reimbursement claims.

40. RJ Health knows that the payors who purchase its drug information resources will use RJ Health’s code prices to set their reimbursement policies and intends for this to occur.

IV. RJ Health’s Misrepresentations

41. On or about April 22, 2015, RJ Health informed BHCP that it intended to reduce the code price for Mirena to \$625. From approximately June 1, 2015 to approximately January 1, 2016, RJ Health represented on its database that the code price for Mirena is \$625. *See* Attachment A.

42. RJ Health purports to follow a set procedure for calculating a code price. This procedure is expressly disclosed to its customers: The “Price Calculation Methodology” webpage states that the code price is based on “published prices.” For a single-source drug like Mirena (i.e., a drug with no generics), the code price corresponds to “the lowest [WAC] of the single source product corresponding to the description of the drug code.” Attachment B. Based on this methodology, when RJ Health disseminated \$625 as the code price for Mirena, RJ Health clearly and intentionally represented to its customers that they should reimburse Mirena based on

a purchase cost of \$625. That representation is patently false. As discussed, the WAC for Mirena was \$810.51, not \$625.

43. As a result of RJ Health's misrepresentations, several health insurers and other payors lowered the reimbursement level they would pay for Mirena to \$625. On information and belief, payors that lowered reimbursement for J7302 to \$625 include Aetna, Anthem Blue Cross Blue Shield CT, Anthem Blue Cross Blue Shield ME, Anthem Blue Cross Blue Shield NH, Blue Cross Blue Shield Mass, Blue Cross Blue Shield GA (Anthem), Blue Cross Blue Shield NC, Blue Cross Blue Shield RI, Blue Cross Blue Shield SC, CDPHP, Cigna, Connecticare (Emblem), Florida Blue, Harvard Pilgrim, HMSA (BCBC Hawaii), Independence Blue Cross, Medical Mutual, Premera, and Wellmark. Those changes were made between July and October 2015, and they were made in reliance on the misleading "code price" that RJ Health disseminated for J7302 starting on June 1, 2015.

44. Health care providers seeking reimbursement from those payors would only be able to obtain reimbursement based on a code price of \$625 even though their actual costs were based on Mirena's WAC of \$810.51. In other words, they would lose money each time they prescribed Mirena.

45. RJ Health knew that under-reimbursement would occur. BHCP warned RJ Health in April and May of 2015. Based on documents obtained from RJ Health in discovery, at least one payor provided a similar warning. On May 19, 2015, a representative from Cigna informed RJ Health that "it would be best to treat [Mirena and Liletta] as separate codes due to the different pricing and different durations." In June 2015, the RJ Health employee responded that RJ Health "did take into account your previous comments about possibly coding Liletta" to a

different code, but nonetheless “opted to code them both to J7302.” The payor replied on June 15, 2015: “*wouldn’t this cause MD’s to lose money if they use Mirena?*”

46. RJ Health also knew that under-reimbursement did in fact occur, based on documents obtained from RJ Health in discovery. For example, a representative from CVS Health /CVS Specialty wrote to RJ Health: “[c]an you please review or escalate this to someone who can answer my question about Mirena. *We are getting under paid because of this from our payors.*”

47. If BHCP took no mitigating action, RJ Health’s conduct would have caused serious harm to patients, healthcare providers, and payors. The financial loss would essentially have forced providers to stop using Mirena, even if they believed that Mirena is the better option for their patients. Many women would have been denied access to Mirena, even those with heavy menstrual bleeding, which Liletta is not approved to treat. This would result in women being switched to other forms of birth control (or none), which could cause increases in the rate of unintended pregnancies. It also could drive market share to Liletta, which is more expensive than Mirena on a monthly basis.

48. Without mitigating action, in addition to serious financial losses, BHCP would have faced a dramatic loss of market share and goodwill when healthcare providers could not obtain adequate reimbursement for Mirena. BHCP’s reputation with patients, providers, and others also could be irreparably harmed if healthcare providers could not obtain adequate reimbursement for Mirena.

49. To mitigate the harms caused by RJ Health’s wrongful conduct, BHCP was forced to temporarily discount its price for Mirena to match the price of Liletta, even though Liletta has a duration of use of only three years rather than five. This forced discount has caused

BHCP damages of tens of millions of dollars. These damages are ongoing, due to the time and cost involved in needing to unwind the forced discount caused by RJ Health's false code price.

50. RJ Health has presented two purported defenses, both meritless. First, RJ Health has asserted that, although it listed the code price for Mirena as \$625, its database elsewhere showed the actual price of Mirena. But, even if this is true (and RJ Health has refused and continues to refuse Bayer access to the database to confirm), the code price is the price that is automatically uploaded by health insurance plans and other payors; the other information is not. Moreover, just as a retraction on page D-19 of a newspaper does not justify a willful misstatement on the front page, RJ Health's purported correction falls short: RJ Health's database still contained a materially false statement that has injured Bayer.

51. Second, RJ Health has argued that both Mirena and Liletta fell within the literal terms of the descriptor of the "J Code" maintained by the Centers for Medicare & Medicaid Services ("CMS"). This is irrelevant. CMS does not dictate the prices of these products, and it does not publish a "code price" for any J Code. *See CMS, HCPCS Level II Coding Procedures*, at 2 (Sept. 6, 2012) ("HCPCS is a system for identifying items and services. It is not a methodology or system for making coverage or payment determinations, and the existence of a code does not, of itself, determine coverage or non-coverage for an item or service. While these codes are used for billing purposes, decisions regarding the addition, deletion, or revision of HCPCS codes are made independent of the process for making determinations regarding coverage and payment."). RJ Health creates those "code prices" and disseminates them to its customers for commercial gain. RJ Health alone is responsible for the accuracy of those representations.

52. In any event, CMS considered whether to revise the descriptor for the J Code and ultimately decided to create two new J Codes distinguishing Mirena and Liletta based on approved duration. The CMS process involves three steps—first, a preliminary recommendation is made by a working group known as the HCPCS Workgroup. Then, a public meeting is convened to provide stakeholders with an opportunity to comment. After the meeting, a final decision is made by CMS when the annual code updates are published in November. Here, the Workgroup preliminarily recommended against any change to the code descriptor for J7302 on the ground that the descriptor was sufficient to accurately describe *Mirena*. See HCPCS Agenda Item #18 (May 8, 2015), <http://go.cms.gov/1KS7mjQ> (“Existing code J7302 . . . adequately describes the product that is the subject of this request.”). At the public meeting, however, a Medicaid representative spoke in support of the need for revisions in light of the introduction of *Liletta*. He stated: “Clinically speaking, these are two different delivery systems, where one is able to deliver the drug over 5 years, and the other is able to deliver the drug over 3 years. . . . And so to have the same J Code for essentially two different delivery systems . . . clinically doesn’t make sense.” HCPCS Public Meeting, 1:23:15-1:24:04 (May 8, 2015), *available at* <https://www.youtube.com/watch?v=xS1HRA22d-I>.

53. Effective January 1, 2016, CMS discontinued the use of HCPCS code J7302 for 52 mg dose, levonorgestrel-releasing intrauterine contraceptive systems. It has created two new J Codes whose descriptors distinguish the drugs based on approved duration. J7297 is for 52 mg dose, levonorgestrel-releasing intrauterine contraceptive systems approved for 3 year duration (which covers Liletta) and J7298 is for 52 mg dose, levonorgestrel-releasing intrauterine contraceptive systems approved for 5 year duration (which covers Mirena). See Centers for

Medicare & Medicaid Services, CMS.gov, 2016 Alpha-Numeric HCPCS File, *available at* <https://goo.gl/gKKHkl>.

54. RJ Health has since revised its database to include these two new codes, and does not currently list the same “code price” for Mirena and Liletta.

COUNT I

LANHAM ACT, 15 U.S.C. § 1125(a)(1)

55. The allegations in Paragraphs 1 through 54 are incorporated here by reference.

56. The Lanham Act, 15 U.S.C. § 1125(a)(1)(B) prohibits the use in commercial advertising or promotion of “any word, term, name, symbol or device, or any combination thereof, or any . . . false or misleading description of fact, or false or misleading representation of fact” that “misrepresents the nature, characteristics, qualities, or geographic origin of his or her or another person’s goods, services, or commercial activities.” The Lanham Act also authorizes “any person who believes that he or she is or is likely to be damaged by” such a violation to a civil action for compensatory damages.

57. Relief authorized in a civil action under the Lanham Act also can include injunctive relief, disgorgement of profits, trebled damages, court costs, legal fees, pre-judgment interest, and post-judgment interest. *See* 15 U.S.C. §§ 1116(a), 1117(a)(1)-(3).

58. RJ Health has violated § 1125(a)(1)(B) by conflating Mirena and Liletta and listing the same price for both of them.

59. In addition, RJ Health has misrepresented the nature, characteristics, and qualities of its own drug information resources. RJ Health claims in its commercial advertising and promotion that its drug information resources are accurate and based on published prices, when they clearly are not with respect to Liletta and Mirena.

60. These misrepresentations are material. RJ Health makes such representations to induce payors to purchase its products. Payors would not do so if they knew that RJ Health was disseminating inaccurate information that was inconsistent with industry standard practices and, indeed, contrary to RJ Health's claimed methodology.

61. These misrepresentations have harmed and will harm BHCP. RJ Health's claims and drug information resources falsely informed payors that Mirena reimbursement is based on a WAC of \$625, which has forced BHCP to temporarily discount Mirena to ensure that healthcare providers that purchase and bill for Mirena do not lose money on each prescription. BHCP also may be harmed through the diversion of sales of Mirena, and by loss of goodwill associated with Mirena.

62. BHCP therefore is entitled, under the Lanham Act, to disgorgement of RJ Health's profits, compensatory and trebled damages, court costs, legal fees, pre-judgment interest, and post-judgment interest.

COUNT II

CONNECTICUT UNFAIR TRADE PRACTICES ACT, Conn. Gen. Stat. § 42-110b(a).

63. The allegations in Paragraphs 1 through 62 are incorporated here by reference.

64. The Connecticut Unfair Trade Practices Act provides that "[n]o person shall engage in unfair methods of competition and unfair or deceptive acts or practices in the conduct of any trade or commerce." Conn. Gen. Stat. § 42-110b(a).

65. RJ Health has violated the Connecticut Unfair Trade Practices Act. First, RJ Health has made materially misleading representations concerning its own products and their accuracy.

66. Second, RJ Health's products contained misrepresentations regarding Liletta and Mirena by conflating them and listing the same price for both of them.

67. RJ Health's conduct constitutes an unfair or deceptive trade practice because these claims are false and misleading. They also are material. RJ Health makes such representations to induce payors to purchase its products. Payors rely on these representations in determining the amount to reimburse healthcare providers, which in turn influences whether those providers are able to purchase Mirena.

68. RJ Health's conduct constitutes an unfair trade practice because it offends public policy, is immoral, unethical, oppressive, or unscrupulous, and will cause substantial injury to consumers and businesspersons. RJ Health has made materially misleading representations concerning Liletta and Mirena, as well as materially misleading representations concerning RJ Health's own products, as explained in the allegations above.

69. RJ Health's conduct also offends public policy and causes substantial injury to consumers by threatening the availability of Mirena, a beneficial product relied upon by women across the U.S. to prevent unintended pregnancies.

70. RJ Health's conduct causes substantial injury to BHCP, by misrepresenting the cost and attributes of its product, Mirena, thereby forcing BHCP to sell Mirena at a significant discount, and causing diversion of sales and loss of goodwill.

71. These injuries are substantial and not outweighed by any countervailing benefits to consumers.

72. RJ Health's conduct was carried out in the course of its trade or commerce, providing its reimbursement code website and database services to its clients.

73. RJ Health is a limited liability company, and is therefore a "person" within the meaning of the CUTPA.

74. As required by the statute, BHCP is providing a copy of this complaint to the Connecticut Attorney General and Commissioner of Consumer Protection simultaneous with the filing of this complaint.

75. BHCP has suffered and will continue to suffer ascertainable monetary losses, as well as loss of goodwill and market share, due to RJ Health's conduct. BHCP seeks actual damages, punitive damages, disgorgement, attorney fees and costs, and pre- and post-judgment interest.

COUNT III

TORTIOUS INTERFERENCE WITH BUSINESS RELATIONSHIPS

76. The allegations in Paragraphs 1 through 75 are incorporated here by reference.

77. The common law prohibits tortious interference with business relationships.

78. BHCP has business relationships, including both contractual and beneficial relationships, with purchasers of Mirena, including distributors, HMOs, hospitals, physicians, and other healthcare providers who purchase Mirena to provide to their patients.

79. BHCP had a reasonable business expectancy of selling additional units of Mirena to these purchasers based on Mirena's WAC at the time of \$810.51.

80. RJ Health knew that BHCP had such business relationships with purchasers of Mirena.

81. RJ Health intentionally and tortiously interfered with BHCP's business relationships with these purchasers by misrepresenting to payors the cost and value of Mirena as explained in the allegations above, thereby causing payors to refuse to reimburse the purchase of Mirena based on its correct WAC.

82. Because of this tortious interference, BHCP could no longer sell Mirena to these purchasers based on its correct WAC, and was wrongfully forced to offer temporary discounts to address RJ Health's publication of a false code price of \$625.

83. RJ Health has no legitimate justification for its interference.

84. BHCP has suffered and will continue to suffer actual financial losses as a result of RJ Health's interference, including loss in profit from the sales of Mirena, diversion of sales, and loss of goodwill.

85. BHCP is entitled to injunctive relief, monetary damages to recoup the lost benefits of its business expectancies, the consequential damages caused by RJ Health's interference, all lost profits, punitive damages, and attorney fees and costs.

COUNT IV

NEGLIGENT MISREPRESENTATION

86. The allegations in Paragraphs 1 through 85 are incorporated here by reference.

87. The common law prohibits negligent misrepresentation.

88. RJ Health has made misrepresentations concerning Liletta and Mirena, as well as RJ Health's own products, as described above.

89. RJ Health knew or should have known that its statements were false, particularly given that Bayer explained the errors in RJ Health's statements in several letters and in-person meetings, as described above.

90. Payors reasonably relied on RJ Health's misrepresentations in making their reimbursement decisions, because RH Health holds out its products as the industry standard for proper claim coding and processing.

91. Payors relied on RJ Health's misrepresentations regarding the "code price" for Mirena in lowering the amount they reimburse healthcare providers for purchases of Mirena.

92. Payors' reliance on these misrepresentations caused BHCP pecuniary harm. Because of RJ Health's misrepresentations, numerous Payors, who automatically upload the code price, lowered their reimbursement for J7302 to \$625. On information and belief, these payors include Aetna, Anthem Blue Cross Blue Shield CT, Anthem Blue Cross Blue Shield ME, Anthem Blue Cross Blue Shield NH, Blue Cross Blue Shield Mass, Blue Cross Blue Shield GA (Anthem), Blue Cross Blue Shield NC, Blue Cross Blue Shield RI, Blue Cross Blue Shield SC, CDPHP, Cigna, Connecticare (Emblem), Florida Blue, Harvard Pilgrim, HMSA (BCBC Hawaii), Independence Blue Cross, Medical Mutual, Premera, and Wellmark.

93. Providers who purchased Mirena based on a WAC of \$810.51 would lose money on each use.

94. As explained above, BHCP was forced to temporarily discount its price for Mirena—a discount that caused BHCP to lose approximately \$60 million through the end of 2015, with additional ongoing consequential damages caused by the time and cost involved in unwinding the forced discount.

95. BHCP is therefore entitled to recover monetary damages for negligent misrepresentation.

RELIEF SOUGHT

BHCP respectfully requests that this Court:

- a. Award compensatory damages for any lost sales of Mirena;
- b. Award compensatory damages equivalent to the temporary discount that RJ Health has forced BHCP to adopt for Mirena;
- c. Award trebled and/or punitive damages for RJ Health's misconduct;
- d. Order disgorgement of RJ Health's profits;
- e. Award costs, attorney fees, and pre- and post-judgment interest;

f. Enter any other relief that is just and proper.

Dated: August 1, 2016
Newark, New Jersey

Respectfully Submitted,

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CERTIFICATE OF COMPLIANCE WITH CONN. GEN. STAT. § 42-110g(c)

I hereby certify that, in accordance with Conn. Gen. Stat. § 41-110g(c), I caused a copy of this complaint to be served on the Connecticut Attorney General and the Connecticut Commissioner of Consumer Protection on August 1, 2016. In accordance with instructions provided on the Connecticut Department of Consumer Protection's website, service was made via email to cutpa@ct.gov.

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